

RECEIVED
CENTRAL FAX CENTER
OCT 31 2006

014

REMARKS

The Applicant appreciates the Examiner's thorough review of the application.
Reconsideration and allowance of all claims are requested.

Currently examined claims include claims 9 - 18. Claims 1 - 8 and 19 - 34 have been withdrawn. Claims 9 - 14 and 17 - 18 have been rejected based upon prior art. Applicant appreciates the Examiner's indication that claims 15 and 16 are allowable upon entry of the above amendments to address the claim objections and 35 U.S.C. 112, second paragraph issues raised earlier by the Examiner.

Claim objections.

The claim objections have been corrected as suggested by the Examiner. Amendments to claim 9 have addressed these objections. Withdrawal of the claim objections is requested.

Claims 9 - 18 are patentable under 35 U.S.C. 101.

The Office Action suggests that claims 9 - 18 were not drawn to patentable subject matter. Applicant respectfully disagrees. Applicant has amended the claims to avoid lengthy arguments on this issue with the understanding that such claims can be pursued in the future. Claims 9 - 18 are drawn to statutory subject matter and are patentable under 35 U.S.C. 101. As presently drawn, the claims address a method of determining the presence of a substance in a sample assay. Claim 9 has

BEST AVAILABLE COPY

been amended to more clearly demonstrate that the invention relates to patentable subject matter.

Claim 9 now reads "a tangible medium", which clearly falls within the statutory subject matter of 35 U.S.C. 101.

Therefore, the claims are patentable under 35 U.S.C. 101. The Applicant respectfully requests withdrawal of the rejection.

Claims 9 - 18 are patentable under 35 U.S.C. 112, second paragraph.

Claims 9 - 18 particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 9 - 18 are patentable under 35 U.S.C. 112, second paragraph, and the Applicant respectfully requests withdrawal of the rejection.

Claims 9 - 18 have been amended as suggested by the Examiner. Further amendments have been made to clarify the claim language. For example, claim 9 has been amended to clarify that there is one set of data for each sample. Other typographical and referential errors have been corrected. No new matter has been added by the amendments in this response.

Therefore, claims 9 - 18 are patentable under 35 U.S.C. 112, second paragraph, and the Applicant respectfully requests that the Examiner withdraw the rejection.

OCT 31 2006

Claims 9 - 14 are patentable under 35 U.S.C. 102(b) over Yang et al. (U.S. 6,216,049).

Claims 9 - 18 are patentable over Yang et al ("Yang"). Reconsideration and allowance are requested.

Independent claim 9, as currently amended, claims a tangible medium containing instructions that when executed by one or more processors performs a method for analyzing numerical data pertaining to a sample assay, the sample assay comprising at least one biological or chemical sample, the numerical data comprising one set of data pertaining to each respective sample, each set of data pertaining to each respective sample comprising a plurality of data values, and each set of data representing a condition of each respective sample at a point in time, the method comprising the steps of:

for each set of data, performing the steps of:

assigning respective numerical values to each of the plurality of data values;

initially correcting the respective numerical values;

initially comparing the initially corrected respective numerical values to a threshold value;

subsequently correcting the initially corrected respective numerical values based on whether the initially corrected respective numerical values exceed the threshold value;

subsequently comparing the subsequently corrected respective numerical values to a reference value corresponding to a predetermined assay; and

indicating whether said sample assay has a predetermined characteristic based on the result of the subsequent comparison.

NOVA\3666801.01

14

BEST AVAILABLE COPY

The Applicant respectfully disagrees with the statements in the Office Action that claims 1 and 2 in Yang explicitly teach the limitations of claims 9 and 10. The applied reference does not teach all of the limitations of claims 9 and 10 of the instant invention in claims 1 or 2 or in the specification.

Claim 1 in Yang teaches a method for controlling a system to analyze numerical data pertaining to a sample assay. The Applicant's invention is a novel method for analyzing numerical data related to sample assays that is not anticipated by Yang. Both Yang and the Applicant's invention use unique and distinct methods for analysis.

Claim 1 in Yang requires "mathematically combining" the numerical values to generate a "total value". The total value is then compared to a threshold value for determining the existence of a predetermined characteristic.

This limitation is not found in the Applicant's invention. Claims 9, 10 or any other claims do not teach combining the numerical values mathematically to generate a total value. In contrast, the Applicant's invention uses a two step correction method before comparison of the twice corrected value to a reference value. In the Applicant's invention, the assigned numerical values are corrected, compared to a threshold value, corrected again, and compared again before determining whether the sample assay contains a predetermined characteristic. This process is distinct from the mathematical combination method found in Yang.

Yang does not disclose all of the elements of claim 9. Therefore, independent claim 9 is patentable over Yang.

Dependent claims 10 - 14 add further patentable features to the patentable features of independent claim 9. For example, claim 10, as amended, adds that the assigning respective

numerical values to each of the plurality of data values further comprises arranging the plurality of data values in a time-ordered sequence representative of the respective points in time. Claim 11 adds that the initially correcting step further comprises calculating a correction value based on one or more of the respective numerical values at a beginning of the time-ordered sequence. Claim 12 adds that the initially correcting step further comprises adjusting each of the respective numerical values in relation to adjacent in time respective numerical values in the time-ordered sequence. Claim 13 adds that the initially comparing step further comprises calculating an average value of the initially corrected numerical values and comparing average value to the threshold value. Claim 14 adds that the subsequently correcting step further comprises correcting each of the initially corrected numerical values in relation to adjacent in sequence initially corrected respective numerical values in a time-ordered sequence representative of the respective points in time.

The Applicant respectfully disagrees with the Examiner that the limitations of claims 10 - 14 are found in Yang. For example, claim 2 in Yang requires several additional steps during the assigning of respective numerical values. However, the steps of claims 10, 11 and 12 of the Applicant's invention are unique and distinct from the steps of Yang. Claim 10 in Yang teaches that the assigning step includes "comparing" data values in a sequence to other data values in that sequence. Numerical values are then assigned to the data values based upon the comparing step. Applicant's invention does not perform this comparison. In contrast, Applicant's invention calculates a correction value based on one or more respective numerical values for each data value in the time-ordered sequence. The Applicant's invention does not contain a comparison between data values as found in Kurnik, but instead compares respective numerical values.

Since Yang does not disclose each and every limitation found in claims 9 - 14, there can be no anticipation. Therefore, claims 9 - 14 are patentable over Yang. Applicant respectfully requests that the Examiner withdraw the rejection.

Claims 9 - 11, 13 and 17 - 18 are patentable under 35 U.S.C. 102(b) over Kurnik et al. (*Sensors and Actuators B*, 1999, vol. 60, p. 19 - 26).

Claims 9 - 11, 13 and 17 - 18 are patentable over Kurnik under 35 U.S.C. 102(b).

Reconsideration and allowance are requested.

As indicated above, independent claim 9, as amended, requires a tangible medium containing instructions that when executed by one or more processors performs a method for analyzing numerical data pertaining to a sample assay, the sample assay comprising at least one biological or chemical sample, the numerical data comprising one set of data pertaining to each respective sample, each set of data pertaining to each respective sample comprising a plurality of data values, and each set of data representing a condition of each respective sample at a point in time, the method comprising the steps of:

for each set of data, performing the steps of:

assigning respective numerical values to each of the plurality of data values;

initially correcting the respective numerical values;

initially comparing the initially corrected respective numerical values to a threshold value;

subsequently correcting the initially corrected respective numerical values based on whether the initially corrected respective numerical values exceed the threshold value;

subsequently comparing the subsequently corrected respective numerical values to a reference value corresponding to a predetermined assay; and

indicating whether said sample assay has a predetermined characteristic based on the result of the subsequent comparison.

Kurnik teaches a Mixtures of Experts (MOE) algorithm for determining blood glucose values from raw signal data. See Abstract. Kurnik describes the use of iontophoresis to measure glucose levels non-invasively. See, for example, page 20, Col. 1, first two full paragraphs. Current is measured to determine glucose levels in the patient. See, for example, page 20, paragraph spanning Col. 1 and 2.

Kurnik cannot anticipate the claim because Kurnik does not contain all of the limitations of independent claim 9. Page 6 of the Office Action argues that Kurnik discloses "glucose data values assigned numerical values over time [Fig. 2 and Fig. 4], which correlates to assigning numerical values to a plurality of data values" as in claim 9. Contrary to the arguments in the Office Action, however, Kurnik does not teach assigning respective numerical values to the data values. Fig. 2 and Fig. 4, as cited by the Examiner, describe sensor current vs. elapsed time and blood glucose (mg/dL) vs. elapsed time (h:mm), respectively. Neither figure refers to assigning numerical values as suggested by the Office Action.

Fig. 2 of Kurnik shows raw data without modification. Applicant's invention takes numerical data comprising a set of data for each sample. The sets of data each have a plurality of data values. The data values are then assigned respective numerical values. In contrast, Fig. 2 of Kurnik merely shows the original raw data values taken from the glucose monitor. Kurnik does not assign respective numerical values to data values as in the Applicant's invention, but instead uses the raw data.

Additionally, Fig. 4 of Kurnik merely shows a correlation between use of the Kurnik algorithm and reference measurements. The results of the glucose analysis, shown in Fig. 4 of Kurnik, do not correspond to assigning respective numerical values to data values as in the Applicant's invention. Fig. 4 of Kurnik does not have any relationship to assignment of respective numerical values, but instead merely is a plot of results of an algorithm. As presently understood, during Kurnik's intended use of the MOE algorithm, reference measurements would not be present and no comparison would be made: Fig. 4 simply does not teach assigning respective numerical values.

Kurnik does not disclose each and every element of claim 9 and cannot anticipate the Applicant's invention. Therefore, independent claim 9 is patentable over Kurnik.

Dependent claims 10, 11, 13 and 17 - 18 add further patentable features to the patentable features of independent claim 9. For example, claim 10, as amended, adds that the assigning respective numerical values to each of the plurality of data values further comprises arranging the plurality of data values in a time-ordered sequence representative of the respective points in time. Claim 11 adds that the initially correcting step further comprises calculating a correction value based on one or more of the respective numerical values at a beginning of the time-ordered sequence. Claim 13 adds that the initially comparing step further comprises calculating an average value of the initially corrected numerical values and comparing average value to the threshold value. Claim 17 adds assigning respective time values to the plurality of data values representative of the respective point in time. Claim 18 adds reporting whether the initially corrected numerical values exceed the threshold value.

Because Kurnik does not disclose each and every limitation found in claims 9 - 11, 13 and 17 - 18, Kurnik does not anticipate these claims. Accordingly, claims 9 - 11, 13 and 17 - 18 are patentable over Kurnik. Applicant respectfully requests that the Examiner withdraw the rejection.

NOVA\3666801.01

21

BEST AVAILABLE COPY

RECEIVED
CENTRAL FAX CENTER

OCT 31 2006

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 50-2228, under Order No. 0220187.0150PTUS from which the undersigned is authorized to draw.

Dated: October 31, 2006

Respectfully submitted,

By 

Matthew J. Laskoski
Registration No.: 55,360
PATTON BOGGS LLP
8484 Westpark Drive, 9th Floor
McLean, Virginia 22102
(703) 744-8055
(703) 744-8001 Fax
Attorney for Applicant